



## Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
CitraFlow™ Sodium Citrate 4% Prefilled Syringe	385425E1, 385425-1E1, 3854E1, 38543, 38543-1, 38553, 38555

MANUFACTURER		
Name of company	Address	Representative
MedXL, Inc.	285 Labrosse, Pointe Claire (QC) Canada, H9R 1A3	Omar Boulanouar Quality Operation Supervisor

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	CE certificate number
Intertek Semko AB 0413	41316788-02

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 7	Annex II.3 of MDD 93/42/EEC Council Directive	ISO 13485:2003, ISO 7886-1:1993, ISO 594-2:1998, ISO 14971:2007, ISO 11137-1:2006, ISO 11137-2:2012, ISO 11737-1:2006, ISO 11737-2:2009, ISO 11607-1:2006, ISO 10993-1:2003, ISO 15223-1, 15223-2, EN 980

MedXL declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Omar Boulanouar

**TITLE:** Quality Operation Supervisor

**SIGNATURE:**

**DATE:** 04-07-16





## Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
CitraFlow™ Sodium Citrate 30% Prefilled Syringe	38243, 38243-1

MANUFACTURER		
Name of company	Address	Representative
MedXL, Inc.	285 Labrosse, Pointe Claire (QC) Canada, H9R 1A3	Omar Boulanouar Quality Operation Supervisor

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	CE certificate number
Intertek Semko AB 0413	41316788-02

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 7	Annex II.3 of MDD 93/42/EEC Council Directive	ISO 13485:2003, ISO 7886-1:1993, ISO 594-2:1998, ISO 14971:2007, ISO 11137-1:2006, ISO 11137- 2:2012, ISO 11737-1:2006, ISO 11737-2:2009, ISO 11607-1:2006, ISO 10993-1:2003, ISO 15223-1, 15223-2, EN 980

MedXL declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Omar Boulanouar

**TITLE:** Quality Operation Supervisor

**SIGNATURE:** 

**DATE:** 04-07-16





## Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
CitraFlow™ Sodium Citrate 46.7% Prefilled Syringe	38143, 38143-1

MANUFACTURER		
Name of company	Address	Representative
MedXL, Inc.	285 Labrosse, Pointe Claire (QC) Canada, H9R 1A3	Omar Boulanouar Quality Operation Supervisor

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Molenstraat 15 2513 BH The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax europe@emergogroup.com

REGISTRATION INFORMATION	
Notified Body and ID #	CE certificate number
Intertek Semko AB 0413	41316788-02

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 7	Annex II.3 of MDD 93/42/EEC Council Directive	ISO 13485:2003, ISO 7886-1:1993, ISO 594-2:1998, ISO 14971:2007, ISO 11137-1:2006, ISO 11137- 2:2012, ISO 11737-1:2006, ISO 11737-2:2009, ISO 11607-1:2006, ISO 10993-1:2003, ISO 15223-1, 15223-2, EN 980

MedXL declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Omar Boulanouar

**TITLE:** Quality Operation Supervisor

**SIGNATURE:**

**DATE:** 04-07-16

